REMARKS

This communication responds to the Office Action mailed October 14th, 2009. The Amendment above was made to obtain allowance of allowable subject matter at the earliest possible date. Support for the Amendment can be found throughout the drawings and specification, including Figure 1 and paragraphs 22 and 33 of the application as published.

Rejection under 35 USC § 102

The Examiner has rejected claims 1-4, 19, 20 and 24-25 as being anticipated by Parks et al., U.S. Patent No. 7,025,790 ("Parks").

Applicant traverses the anticipation rejection on the grounds that Parks does not disclose each element of the pending claims. In contrast to Applicant's claimed invention, Parks discloses only total ankle prosthetics, which are multiple piece joint prosthetics whereby each bone making up the joint (i.e., the tibia and talus) has a piece fixed to it. As shown in Figure 15, the implant of Parks includes tibial 40, talar 50, and mobile bearing 60 components. *See col. 9, lines 37-44.* The tibial component 40 is securely attached to the tibia and the talar component 50 is securely attached to the talus, while the mobile bearing component 60 is located between tibial 40 and talar 50 components. *Id.* The remaining embodiments described in Parks all require at least a talar component attached to the talus, and a tibial component attached to the tibia. *See col. 9, line 37-Col. 10, line 24, and Col. 11, line 3- Col. 12, line 3.*

A serious disadvantage of this multiple component total joint prosthesis is that attaching the various components of the prosthesis to the bone is an invasive surgical procedure that requires bone to be removed. Although, as pointed out by the Examiner, the prosthesis disclosed in Parks may require less bone resection than other designs, it still requires bone resection within

the joint site, which requires an invasive surgical procedure. (*See, e.g.*, Figure 4, which shows in dotted lines the portion of the bone that must be removed from both the tibia and the talus before the prostheses can be implanted).

In contrast, Applicant claims an interpositional tibiotalar implant. Applicant has amended the independent claims above to clarify that the implant is *a single piece implant* to further define over the multiple component systems described by Parks. As claimed, this single piece implant has a first major surface that is adapted to be positioned against a tibia and a second major surface adapted to be positioned against a talus. Such an implant does not require multiple pieces that move relative to each other and the corresponding bone resection required by total ankle prosthetics. Parks does not disclose such an implant because, as described above, it requires a component to be fixed to both the tibia and the talus (i.e., more than a single piece implant). Accordingly, the lack of novelty rejection of claim 1, and the claims depending therefrom, should be withdrawn.

Dependent Claim 19

Dependent claim 19 is allowable for the reasons discussed above, and for others as well. By the amendment above, Applicant has amended claim 19 to include that the implant is inserted through an incision anterior to the tibiotalar joint. Such a procedure is minimally invasive in contrast to the invasive procedure required to install the multiple piece prosthesis discussed in Parks. For example, Parks discloses the following to gain access to the joint for its prosthesis:

> To gain lateral access to the ankle joint, the fibula 2 is cut at a point above its lower end and this lower end is moved to the side. See FIG. 2. The distal end of the fibula is reflected down hinged on the posterior talofibular and calcaneofibular ligaments. The syndesmosis, anterior talofibular and part of the calcaneofibular

> ligaments are released from the fibula. The ankle joint is distracted manually or by using an unilateral external fixator applied to the medial aspect. This gives better access to the distal tibia and talar dome surfaces that are to be cut. See FIG. 3.

Accordingly, Parks does not disclose inserting an implant through an incision anterior to the tibiotalar joint, and the rejection of claim 19 should be withdrawn.

Dependent Claim 20

Dependent claim 20 is also allowable for the reasons discussed above, and for others as well. By the amendment above, Applicant has amended claim 20 to provide that the implant is inserted into the tibiotalar joint. In this location, the first major surface of the single piece implant is positioned against the tibia and its second major surface is positioned against the talus, and an integral bead shaped structure proximate the implant's anterior side engages a neck of the talus. As discussed above, Parks does not disclose such an implant because it only discloses multiple component prosthetics; hence no single component of Parks has a first surface positioned against the tibia and a second surface positioned against the talus. Further, the structure disclosed in Parks at col. 9, lines 61-63 and col. 10, lines 14-18 that the Examiner has characterized as the "integral bead" claimed by applications is not retained against the neck of the talus. Rather, as shown in Figure 4, it is inserted into a portion of bone that has been resected to receive it. Accordingly, the rejection of claim 20 should be withdrawn.

Rejection under 35 USC § 103

The Examiner has rejected claims 5-7 as being unpatentable over Parks et al., U.S. Patent No. 7,025,790, in view of Schon U.S. Patent No. 6,572,620. This rejection is traversed for the reasons provided above, and for others as well. Schon discloses an elongated blade 20 to fix ankle bone relative to the tibia. Accordingly, Schon is a joint fixation device, not an interpositional implant that allows the joint to articulate after implantation. Even if Schon could be considered an implant with major surfaces, it still has multiple components as shown in Figures 1 and 2. Hence, Schon adds nothing to remedy the defects of Parks et al. in this regard, and the obviousness rejections of these claims should be withdrawn.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Commissioner is hereby authorized to charge any additional fees required to Deposit Account No. 061910.

Respectfully submitted,

/Matthew J. S. Graham/

Matthew J. S. Graham
Registration No. 54,647

Customer No. 22859
Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7000
Facsimile: (612) 492-7077

4657856_1.DOC